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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/735,408	12/11/2000	Ronald K. Yamamoto	ISC9901U	4638

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EXAMINER

BOUCHELLE, LAURA A

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/735,408

Applicant(s)

YAMAMOTO ET AL.

Examiner

Laura A. Bouchelle

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 and 64-77 is/are pending in the application.
- 4a) Of the above claim(s) 5,9,11-17,30,35,36,40,41,43,44 and 47-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-8,10,18-29,31-34,37-39,42,45,46,64-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
1. Claims, 1-4, 20, 24, 67-71, 73-77 are rejected under 35 U.S.C. 102(e) as being anticipated by Shahidi (US 6167296).
2. Shahidi discloses an apparatus comprising a locating means 105-108 (col. 3, lines 22-27) that is capable of being used to non-invasively locate Schlemm's Canal in an eye that is coupled with a microsurgical device 109 that is capable of being advanced into a tissue space identified with Schlemm's Canal, where the surgical device is under control by the locating means (a computer program is integrated with the locating means and the program provides instruction as to where the surgical instrument is located at a given point during a surgical procedure thereby guiding a surgeon where he should be using the surgical instrument and therefore the location means control where a surgeon should be using the surgical instrument during a procedure). See Figs. 1-8. Further, the locating means comprises a device that is capable of being used for ultrasound examination of the sclera (col. 7, lines 37-41) or an ultrasound imaging system. See Fig. 4.

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3. Regarding claim 20, Shahidi discloses a microcannula in the form of an endoscope 109 (Col. 4, line 8).

4. Regarding claim 24, Shahidi discloses that the locating means 110, 111, and the microcannula 109 are disposed within a unitary body. See Fig. 1.

5. Regarding claim 32, the microcannula 109 is coupled coaxially with the locating means 115 (ultrasound transducer).

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shahidi in view of Thomas. III et al (US 4911170).

8. Claims 6 and 7 differ from Shahidi in calling for the examination of the sclera with an ultrasound frequency of greater than 10 MHz or at least 40 MHz. Thomas discloses, as does applicant in the background of the invention, an image ultrasound catheter system that uses frequency of 25-50 MHz to image the fine structure of tissues. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the frequency of the

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ultrasound of Shahidi to be 25-50 MHz as taught by Thomas so that the finer structure of the tissues could be visualized.

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shahidi in view of Bernstein (US 6132699).

10. Claim 8 differs from Shahidi in calling for the locating means to utilize and ultrasound contrasting tracer. Bernstein teaches the use of an ultrasound contrast introduced into the body of interest to enhance detection and observation of certain physiological and pathological conditions (Col. 1, lines 29-33). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Shahidi to include the use of an ultrasound contrast agent as taught by Bernstein to enhance detection and observation of certain physiological and pathological conditions.

11. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shahidi in view of LeBlanc et al (US 5989189).

12. Claim 10 differs from Shahidi in calling for the locating means to comprise a transducer assembly with signaling means for directing the transducer location. LeBlanc teaches the use of an ultrasound transducer with a signaling means in order to detect, not only typical eye structures such as the cornea, retina, sclera, etc, but also aberrations such as tumors and blood trapped within an eye's vitreous (Col. 1, lines 16-27). It would have been obvious to one of ordinary

skill in the art at the time of invention to modify the invention of Shahidi to incorporate a transducer assembly with a signaling means as taught by LeBlanc in order to detect the above mentioned structures in the eye.

13. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shahidi in view of Schachar (US 6146366).

14. Claim 18 differs from Shahidi in calling for the surface of the locating means to be curved to approximate the surface of the eye. Schachar teaches the use of a device used for the treatment of eye disorders, which has a surface that contacts the eye that is curved in order to provide an approximate match for the curvature of the surface of the eye (Col. 9, lines 53-56). See Fig. 6. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Shahidi so that the tissue contacting surface is curved as taught by Schachar to provide an approximate match for the curvature of the surface of the eye.

15. Claims 19, 27-29, 31, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shahidi in view of Steen et al (US 5984904).

16. Claim 19 differs from Shahidi in calling for the tissue-contacting portion to incorporate a circumferential raised portion to maintain placement of a coupling fluid over a transducer face. Steen teaches the use of a surgical instrument to perform eye surgery which contains several raised portions in the form of an array of protuberances projecting from an interior wall surface

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and spaced apart in longitudinal and transverse directions so as to define a network of generally uniform channels extending between adjacent protuberances 40 for fluid flow about each protuberance in a longitudinal and transverse direction (Col. 4, lines 7-12). See Figs. 4-7. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Shahidi to have protuberances as taught by Sheen to form a channel to maintain placement of a fluid around the entire circumference of an instrument.

17. Claims 27 and 29 differ from Shahidi in calling for the microcannula or the inner cannula to incorporate a cutting tip to penetrate the sclera of the eye. Steen teaches the use of a microcannula or inner cannula 26 with a cutting tip 16 capable of cutting the sclera of the eye during a surgical procedure of the eye (Col. 4, line 8). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Shahidi to include a cutting tip as taught by Sheen to remove the sclera during a procedure on the eye.

18. Claims 28 and 31 differ from Shahidi in calling for the microcannula to comprise a flexible outer sheath and an inner cannula. Sheen teaches the use of a pliable outer sheath 10 and an inner cannula 26 to facilitate insertion into the eye during surgery (Col. 2, lines 55-58). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Shahidi to include a flexible outer sheath and an inner cannula as taught by Sheen to facilitate insertion of the device into the eye during surgery.

19. Claim 46 differs from Shahidi in calling for the device to have a surgical tool for cutting tissues. Steen teaches the use of a construct 16 delivered through a microcannula 26, which comprises a surgical tool for cutting tissues in order to remove the natural lens from an eye

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during a surgical procedure. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Shahidi to include a surgical tool for cutting tissues as taught by Sheen to enable the device to remove tissue from the eye during a surgical procedure.

20. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shahidi. Shahidi discloses a microcannula 109 (Col. 4, line 8) but does not specify a size of less than 200 microns. It would have been obvious to one of ordinary skill in the art to modify the microcannula of Shahidi to limit the size to be less than a specific measurement, such as 200 microns, in order to accommodate the use of the cannula in a correspondingly small space.

21. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shahidi in view of Imling et al (US 6203499).

22. Claims 22 and 23 differ from Shahidi in calling for the microcannula to be coupled to the locating means at an adjustable angle such as an angle between 0 and 30 degrees. Imling teaches the use of a multiple angle needle guide that can be coupled to an imaging system (Col. 1, lines 36-44) in order to allow the needle to be adjusted to any angle, such as one between 0 and 30 degrees. See Fig. 1. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Shahidi to include a multiple angle guide as taught by Imling so that the needle can be coupled to the locating means at an angle between 0 and 30

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degrees to ensure that the needle can be effectively maneuvered in the direction indicated by the locating means.

23. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shahidi in view of Simon (US 4883053).

24. Claim 25 differs from Shahidi in calling for the microcannula to be coupled to the locating means using a clip mechanism. Simon teaches the use of a chop mechanism 68a, 68b to couple a cannula 66 to another device 50 in order to assure that the coupling is secure. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Shahidi to include a clip mechanism as taught by Simon to securely couple the cannula to the locating means.

25. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shahidi in view of Mohr, Jr et al (US 5921954).

26. Claim 26 differs from Shahidi in calling for a distal portion of the cannula to be curved to accommodate a curvature of Schlemm's Canal. Mohr discloses a cannula to be used in treating a myriad of body structures, where the cannula tip 101 may comprise a curved needle-like shape adapted to a surface of curvature of an eye, so the cannula tip 101 can be used easily with on a procedure on the eye (Col. 3, lines 39-42). Therefore, it would have been obvious to one of

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ordinary skill in the art at the time of the invention to modify the cannula of Shahidi by curving the tip of the cannula as taught by Mohr so that it may be used easily with the eye.

27. Claims 32-34, 37, 38, 45, 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shahidi in view of Lynch et al (US 6524275).

28. Claims 32-34 differ from Shahidi in calling for a dilation mechanism on the tip of the cannula. Lynch discloses an inflatable device and method for treating glaucoma that teaches the use of a dilation mechanism on the tip of a cannula 50, which consists of an inflatable sleeve such as a balloon which is placed within Schlemm's canal and the inflatable element of the device is expanded to temporarily stretch and expand the lumen of the canal. At that point, the inflatable element may be used to temporarily occlude outflow through the canal, while physiologic material is injected through another lumen of the device, thereby distending the canal and expanding areas of stenosis within the canal (Col. 3, lines 56-65). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cannula of Shahidi to incorporate a dilation mechanism, such as the inflatable balloon on the tip of the cannula as taught by Lynch for placement within Schlemm's Canal in order to temporarily stretch and expand the lumen of the canal.

29. Claim 38 differs from Shahidi in calling for an implant being delivered into Schlemm's Canal. Lynch teaches an implant being delivered into Schlemm's Canal (Col. 5, lines 4-12) in order to maintain patency within the canal to facilitate the natural drainage of the aqueous humor. Therefore, it would have been obvious to one of ordinary skill in the art to modify the

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invention of Shahidi to include an implant that is delivered into Schlemm's Canal as taught by Lynch in order to maintain patency within the canal the facilitate the natural drainage of the aqueous humor.

30. Claim 45 differs from Shahidi in calling for a construct to be delivered through a microcannula. Lynch teaches a construct being delivered through a microcannula 100 (Col. 5, lines 4-12) to effect a surgical procedure on a trabecular meshwork of the eye (Col. 7, lines 15-19). Therefore, it would have been obvious to one of ordinary skill in the art to modify the invention of Shahidi to include a construct delivered through a microcannula as taught by Lynch in order to effect a surgical procedure on a trabecular meshwork of the eye.

31. Claims 39 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shahidi in view of Lafont et al (5,957,975).

32. Claims 39 and 42 differ from Shahidi in calling for the use of an expandable or biodegradable stent. Lafont teaches the use of an expandable biodegradable stent for the purpose of enlarging a lumen or canal within the body that will degrade within the body and eliminates the need for removal of the stent. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Shahidi and add an expandable stent as taught by Lafont for the purpose of enlarging a lumen or canal within the body, such as Schlemm's Canal that will degrade with the body and eliminate the need for removal of the stent.

Response to Arguments

33. Applicant's arguments filed 4/21/06 have been fully considered but they are not persuasive. Applicant argues that the device of Shahidi is of no practical use in the current application because of the structural limitations of the eye and the inaccuracy of the imaging method. However, the examiner finds the Shahidi device to be capable of performing the requisite operation with respect to locating Schlemm's Canal and imaging accuracy and finds no positive recitation of a limitation in the claims that would suggest otherwise. For further reference see Shahidi (Col. 11, line 57 – Col. 12, line 21).

Conclusion

34. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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